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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,007

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EXAMINER

OU, JING RUI

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,007	<b>Applicant(s)</b> MIALHE, CLAUDE	
	<b>Examiner</b> JING OU	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This action is responsive to preliminary amendment filed on August 07, 2006.

Claims 1-16 are pending. Claim 1 is independent.

#### ***Priority***

2. The foreign priority claim filed on 03/22/2004 was not entered because the foreign priority claim was not filed during the time period set forth in 37 CFR 1.55(a)(1). For original applications filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the time period is during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. For applications that have entered national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT. See 37 CFR 1.55(a)(1)(ii). If applicant desires priority under 35 U.S.C. 119(a)-(d), (f) or 365(a) based upon a prior foreign application, applicant must file a petition for an unintentionally delayed priority claim (37 CFR 1.55(c)). The petition must be accompanied by (1) the claim (i.e., the claim required by 35 U.S.C. 119(a)-(d) and (f) and 37 CFR 1.55) for priority to the prior foreign application, unless previously submitted; (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.55(a)(1) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition

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should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

### ***Claim Objections***

3. Claims 1-16 are objected to because of the following informalities: the term "device" in the preamble of each claim should be replaced by "system" since claim 1 includes an implant and an apparatus for delivering the implant. In line 15 of claim 1, the phrase "it is provided" is improperly written and should be re-written properly. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 11, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Vargas et al (US Pub. No. 2002/0042622).

In regard to Claims 1-5, 11, 15 and 16, Vargas et al discloses an implant delivery system, comprising: a vessel dilation device (deployment system 150 excluding anastomosis device 120, Fig. 5) with an outer envelope (outer trocar, 152, Fig. 5) and a tapered end piece (tapered end piece of 152, Fig. 5), whereby the end piece consists of a nose (the tapered end piece of 152 is a nose), means for opening the nose, consisting of at least two longitudinal slots which divide the nose into several segments (Figures 5 and 6 and Para. [0062]); an implant (anastomosis device 120, Fig. 5), the implant

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includes an expandable element (distal end of 120 presses against the internal wall of the distal end of the outer envelope when 120 is pushed out of the 152, Fig. 5) which presses against the internal wall of the outer envelope; means of translation, the means of translation include an inner sheath (holder tube, 154, Fig. 5); the implant includes a second, hollow expandable element (shoulders 134, Fig. 5) and a hollow intermediate section (the intermediate section of 120 must be deformation by twisting, Fig. 5); a grip (distal fitting, 184, Fig. 5) that is an integral part of the outer envelope; a grip (medial fitting, 184, Fig. 5) that is an integral part of the inner sheath, and a plunger (expander tube, 156, Fig. 5).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Garza et al (US Pat. No.: 4,665,918) in view of Martinez et al (US Pat. No.: 5,593,412).

In regard to Claims 1-16, Vargas et al discloses an implant delivery system, comprising: a vessel dilation device (combination of prosthesis delivery catheter 18, sheath 50, and guiding catheter 78, Fig. 1) with an outer envelope (guiding catheter, 78, Fig. 1); an implant (prosthesis, 25, Fig. 5), the implant includes an expandable element (distal portion of the prosthesis, Fig. 5); means of translation, the means of translation include an inner sheath (sheath, 50, Fig. 5); the implant includes a second, hollow expandable element (the proximal end of the prosthesis 25, Fig. 5) and a hollow intermediate section (the intermediate section of the prosthesis 25 is deformable by twisting since it is an expandable stent, Fig. 5); a grip (hub, 86, Fig. 1) that is an integral part of the outer envelope; a grip (hub, 64, Fig. 1) that is an integral part of the inner sheath, a removable spacer (locking arms 72, Fig. 7, the combination of the locking arms 72 and 44 restrict the relative positions of hub 86 and hub 64 and a portion of locking arms 72 is situated between the hubs 86 and 64), a plunger (combination of proximal portion 22 and portion 24, Fig. 1), a grip (hub, 30, Fig. 1) that is an integral part of the plunger, a second removable spacer (hubs, 44, Fig. 7), means (the separated portions 58 is capable of rotating the inner sheath and thus adjusting the angle of the inner sheath) of adjusting the angle of the inner sheath, and a central channel (the channel of guiding catheter, Fig. 1) along the line of the outer envelope.

Vargas et al does not appear to disclose that the outer envelope has a tapered end piece and detailed structures of the end piece.

However, Martinez et al explicitly discloses an implant delivery system, comprising of an outer envelope (sheath, 18, Fig. 1) having a tapered end piece (distal

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end portion 32 is tapered, Fig. 1) at the distal end of the outer envelope and an implant have expandable portion (stent, Fig. 10) that is pressed against the sheath, whereby the end piece consists of a nose (the tapered distal end portion 32 is nose, Fig. 1) and means for opening the nose, consisting of at least two longitudinal slots (weakened areas, 41-45, Fig. 2A) which divide the nose into several segments (sections, 51-55, Fig. 2A), nose segments are joined as required along the slots when the nose is closed (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); temporary connector by slots between segments (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); and the nose includes a central residual passage (central opening, 50, Fig. 2A).

Vargas et al and Martinez et al are analogous art because they are from the same field of endeavor, implant delivery system.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Vargas et al and Martinez et al before him or her, to modify the implant delivery system of Vargas et al to include an outer envelope having a tapered end piece and detailed structures of the end piece as taught by Martinez et al.

The suggestion/motivation for doing so would have been to protect the implant from immature deployment and control the deployment of the implant. Until the delivery device reaches a target site, the distal end portion of the sheath is softened by exposing to a warm, physiologically compatible liquid, thereby to allow for retraction of the sheath and deployment of the implant (Martinez et al, Col. 3, lines 24-42). Applicant should have noted that the tapered end piece is old and well-known in the art. Furthermore, it

is old and well-known that the nose includes a shape memory, which would facilitate the withdrawn of the delivery system from body or enable addition insertion of another implant without withdrawn the sheath out of the body.

Therefore, it would have been obvious to combine Martinez et al with Vargas et al to obtain the invention as specified in the instant claims.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goicoechea et al (US Pat. No.: 5,938,696)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

/Darwin P. Erezol/  
Primary Examiner, Art Unit 3773